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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,416	12/20/1999	PIETER DE HAAN	0/97286US	2292

31846 7590 11/26/2003

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/26/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

08

Office Action Summary

Application No.

09/446,416

Applicant(s)

HAAN ET AL.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. The claim objection is overcome by the amendment

Claim Rejections - 35 USC § 112

1. The 112 Rejections are withdrawn because "the door" has been removed from the claims, therefore making the rejection moot.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaldany (USPN 5562613).

Kaldany discloses a preloadable implantation device comprising a needle (104), a body (16) and an elongated part, a plunger (108), the periphery of the plunger defining a channel, and a chamber (104b). (Figures 3, 6, 7, 8, 9, 10 and entire reference)

Wherein the needle (104a) and the plunger (108a) are chamfered.

Wherein the outside is closed after preloading. (Figures 3,6)

4. Claims 1, 3, 5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by J. Muir (USPN 1655158).

Muir discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, and a chamber. (Figures 1-10 and entire reference)

Wherein the needle is chamfered. (Figures 4-9)

Wherein the outside is closed after preloading. (Figures 4-8)

5. Claims 1, 3-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wiegerinck (USPN 5,405,324).

Wiegerinck discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, and a chamber. (Figures 1-3 and entire reference)

Wherein the needle and plunger are chamfered. (Figures 1-3)

Wherein the outside is closed after preloading. (Figures 1-3)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir as applied to claims 1, 3, 5, 7, 8 above, and further in view of Wiegerinck.

Muir discloses the claimed invention but fails to disclose the implant is a hormonal implant.

Wiegerinck (USPN 5405324) discloses the implant as a hormonal implant.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Muir with Wiegerinck because it is well known in the medical art to use different types of medication with different types of applications, such as using hormonal pills or tablets, as stated in Wiegerinck. (Column 1, lines 1-25)

Therefore, it would have been obvious to combine the teachings of Muir with Wiegerinck to obtain the invention as specified in claims 1, 3-9.

8. Claims 1, and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany as applied to claim 1, 3, 5, 7, 8 above, and further in view of Wiegerinck.

Kaldany discloses the claimed invention but fails to disclose the implant is a hormonal implant.

Wiegerinck (USPN 5405324) discloses the implant as a hormonal implant.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Kaldany with Wiegerinck because it is well known in the medical art to use different types of medication with different types of applications, such as using hormonal pills or tablets, as stated in Wiegerinck. (Column 1, lines 1-25)

Therefore, it would have been obvious to combine the teachings of Kaldany with Wiegerinck to obtain the invention as specified in claims 1, 3-9.

Response to Arguments

9. Applicant's arguments filed 10/22/03 have been fully considered but they are not persuasive.

10. The examiner disagrees with the interpretation of the prior art of with regards to Muir and Kaldany.

11. The examiner interprets Kaldany to have "chamfered tip" to be a tip that is bevel (The examiner used *The American Heritage® Dictionary of the English Language, Fourth Edition* to find the definitions of all the terms) and this is taught in Column 5, line 40. Next the examiner interprets Kaldany to have a chamber radially outside the channel, which is shown in Figures 7-10, wherein the channel is the lumen inside the hollow needle (104) and the chamber is radially outside the channel (104b). The examiner interprets radially to mean moving or directed along a radius, and the radius is at 180 degrees from the channel. The Applicant is reading limitations into the claim from the specification because there is no mention of the chamber being on or above the channel.

12. With regards to the Muir the hollow needle is reference number 5, with a chamfered tip reference number 8, (Page 2, Column 1, lines 49-55) and the trocar needle can be used as the plunger and the trocar has a chamfered tip as well. (Page 2, Column 1, lines 49-55; Page 2, Column 2, line 110)

13. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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14. In response to applicant's arguments, which are a recitation of the intended use of the claimed invention, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto
Art Unit 3763
November 19, 2003



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700